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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. 09/123,620

filed 7/28/98

Examiner K.K. Fonda

ATTY. DOCKET NO. HEBVR-5

Group Art Ubit ~~1814~~ 1623

In re. application of Howard E. Elford;

THERAPEUTIC PROCESS FOR INHIBITION OF NF- $\kappa$ B

COMMISSIONER OF PATENTS AND TRADEMARKS

WASHINGTON DC 20231

2/2/00  
K.K.F.  
8/20/00

AMENDMENT TO THE CLAIMS

NE Claim 1, line 2 beneath the formula, after "drugs" replace "and"  
with or an.

line 3, beneath the formula, replace "salts" with

salt

Claim 2, line 2, replace "includes, but not limited to" with  
comprising.

Respectfully submitted

*James L. Rowe*

James L. Rowe, Atty. for Appellant

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Dated:

6/28/00



GAU-1614

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant: Howard E. Elford

Serial No. 09/123,620

Filed: 7/28/98

Group Art Unit 1614

For: THERAPEUTIC PROCESS FOR INHIBITION

Examiner K.K. Fonda

OF NF- $\kappa$ B

Docket No. HEBVR-5

Commissioner of Patents and Trademark

Washington DC 20231

RESPONSE TO OFFICE LETTER

The following paragraphs are in response to the Examiner's comments concerning the format and contents of Appellant's Brief on Appeal.

REJECTION UNDER 35 USC 112 1st Para.

Claims 9-11 were rejected under 35 USC 112 Para.1 on the ground that the claimed subject matter was not described in the specification. The Examiner then suggested that, as a method of overcoming this rejection, Appellant could amend the specification to add the subject matter of these claims since the terms were in the claims as originally filed and therefore, the amendment would not contain new matter. In an amendment to the specification contained in the Response to Final Rejection dated 11/15/99, Appellant did precisely that. Thus Appellant does not understand the Examiner's remarks since the rejection should have been overcome by said amendment to the specification made in accordance with the Examiner's suggestion. In any case, Appellant should have discussed this amendment in the Brief on Appeal as filed, and trusts that the above remarks will clarify his response to the Final Rejection.

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REJECTION UNDER 35 USC 112 2nd. Para.

Claim 1 is held to be indefinite on the ground that the term "NF- $\kappa$ B inhibiting amount" has no art-recognized meaning. As stated in the Brief on Appeal, this rejection is not well taken. There is no requirement in the law that a human clinical trial of a potential drug be carried out and the dose which can be administered to a human suffering from a particular condition be determined prior to filing an application covering the use of said drug for treating said disease. As previously stated, it would be well within the skill of the art for a skilled practitioner to ascertain an effective human dose for a drug, given the animal studies already of record. Furthermore, there have been sufficient mammalian experiments involving Didox, Trimidox and Amidox, Appellant's drugs of choice in various conditions, so that the establishment of an effective dose to inhibit NF- $\kappa$ B should be a routine procedure.

Claim 1 is also rejected under 35 USC 112 2nd para. for failing to claim the invention in proper terms. The accompanying amendment changes the terminology so that Appellant now claims "the administration of a drug of the formula, an acyl deriv. or a pharmaceutically-acceptable salt thereof". It is submitted that the alternative language no longer requires administration of a drug combination and should remove any remaining doubts regarding ambiguity of the claim.

Claim 2 was rejected under 37 USC 112 2nd para. as being indefinite. The objected-to language has been cancelled by the accompanying amendment which uses the term "comprises" as suggested by the Examiner.

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Appellant submits that Claims 1-2 are no longer subject to a rejection under 35 USC 112 1st or 2nd para. and that the Brief on Appeal should be forwarded to the Board of Appeal.

Respectfully submitted.



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6/20/02